PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

PROPRIETARY NAME AND DOSAGE FORM

PREXOLAN IM

Powder for solution for injection

Read all of this leaflet carefully before PREXOLAN IM is administered to you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

WHAT PREXOLAN IM CONTAINS

The active substance in PREXOLAN IM is olanzapine 10 mg per vial.

The other ingredients are citric acid monohydrate, maltose.

Contains sugar: Maltose 72 mg

Diluent is sterile water for injection.

WHAT PREXOLAN IM IS USED FOR

PREXOLAN IM belongs to a group of medicines called antipsychotics.

PREXOLAN IM is used for the control of agitation and disturbed behaviour in patients with schizophrenia. It is also used in patients with acute mania (feeling elated or over-excited which causes unusual behaviour) when oral therapy is not appropriate.

BEFORE YOU RECEIVE PREXOLAN IM

Do not receive PREXOLAN IM:

- If you are allergic to PREXOLAN IM or any of the other ingredients contained in PREXOLAN IM.
- If you have or likely to have narrow-angle glaucoma (increased pressure in the eye).
- If you are under the age of 18 years. The effects of PREXOLAN IM have not been tested in children.
- If you are > 80 years of age.

Take special care with PREXOLAN IM:

- PREXOLAN IM may cause unusual movements mainly of the face, tongue, lips, trunk, arms and legs. If this happens after you have been given PREXOLAN IM tell your doctor immediately.
- The use of PREXOLAN IM in elderly patients with mental deterioration (dementia) is not recommended as it may have serious side effects.
- You should tell your doctor if you suffer from a slow heartbeat if you had a recent heart attack or uncompensated heart failure (a condition in which the heart can no longer pump enough blood to the rest of the body).
- You should tell your doctor if you smoke.

You should also tell your doctor as soon as possible if you suffer from any of the following illnesses after you receive PREXOLAN IM:

- Slower heart beat
- Fainting
- Temporarily stop breathing
- Irregular heart beat
- Calming effect, relaxation, sleep induction (sedation)
- Confusion, disorientation, agitation, anxiety; the ability to think, concentrate, formulate ideas, reason and remember is affected (delirium)
- Difficulty in speaking
- Difficulty in controlling movements
- Aggression
- Dizziness
- Weakness
- High blood pressure
- Fits.

Receiving PREXOLAN IM with food and drink:

Do not drink any alcohol if you have been given PREXOLAN IM as PREXOLAN IM and alcohol together may make you feel drowsy.

The consumption of food does not have an effect on PREXOLAN IM.

You may receive PREXOLAN IM with or without food.

Pregnancy and breastfeeding:

You should not receive PREXOLAN IM if you are pregnant or breastfeeding.

If you are pregnant or breastfeeding your baby please consult your healthcare provider for advice before receiving PREXOLAN IM.

Tell your doctor if you are or think that you may be pregnant.

Driving and using machinery:

PREXOLAN IM may cause drowsiness, trouble in thinking, trouble in controlling movements, or trouble in seeing clearly. Make sure you know how PREXOLAN IM affects you before you drive, use machines, or do other jobs that require you to be alert, well-coordinated, or able to think or see well.

Important information about some of the ingredients of PREXOLAN IM:

PREXOLAN IM contains maltose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Taking other medicines with PREXOLAN IM:

Always tell your healthcare provider if you are taking any other medicines (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- PREXOLAN IM may add to the effects of alcohol and other central nervous system (CNS) depressants (medicines that make you drowsy or less alert). Some examples of CNS depressants are antihistamines (medicines for hay fever, other allergies or colds), sedatives (tranquillisers or sleeping medicine), prescription pain medicine or narcotics, barbiturates (medicine for seizures), muscle relaxants, or anaesthetics, including some dental anaesthetics. Check with your doctor before taking any CNS depressants while you are receiving PREXOLAN IM.

You should tell your doctor if:

- You are taking levodopa (normally given to patients suffering from Parkinson's disease).
- You are taking any antihypertensive medication (used for high blood pressure).
- You are taking fluoxetine (an antidepressant).
- You are taking fluvoxamine (an antidepressant), ciprofloxacin (an antibiotic) or ketoconazole (an antifungal) or antacids, as it may be necessary to change your PREXOLAN IM dose.
- You are taking carbamazepine for epilepsy as it can lower the effect of PREXOLAN IM.
- You are taking medication that lowers blood pressure such as antihypertensives or medicines that cause hypotension as a side effect.
- You are receiving activated charcoal.
- You are receiving lorazepam injections.

HOW PREXOLAN IM WILL BE GIVEN

PREXOLAN IM is for intramuscular use only and should be given in a healthcare facility.

Your doctor or healthcare provider will give the injection and may change to the oral medicine if necessary.

The recommended dose for PREXOLAN IM is 10 mg given as a single injection directly into the muscle.

For elderly patients a lower dose of 2,5 mg to 5 mg per injection is recommended.

If you receive more PREXOLAN IM than you should:

Since a healthcare provider will administer PREXOLAN IM, he/she will control the dosage.

However, in the event of overdosage your doctor will manage the overdosage.

Signs and symptoms with PREXOLAN IM overdose include calming effect, relaxation, sleep induction (sedation), confusion, disorientation, agitation, anxiety, the ability to think, concentrate, formulate ideas, reason and remember is affected (delirium), difficulty in speaking, difficulty in controlling movements, aggression, dizziness, weakness, high blood pressure and fits.

If you miss a dose of PREXOLAN IM:

PREXOLAN IM will be given to you by a healthcare provider. They will ensure that you receive all your doses.

POSSIBLE SIDE EFFECTS

PREXOLAN IM can have side effects.

Not all side effects reported for PREXOLAN IM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PREXOLAN IM, please consult your healthcare provider for advice.

If any of the following happens, stop taking PREXOLAN IM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- If you get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria). This may mean you are having an allergic reaction.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to PREXOLAN IM. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- If you have muscle weakness, tenderness or pain, feel unwell or have a high temperature. You may have a rare but serious illness that can be life-threatening called rhabdomyolysis,
- if you have a combination of fever, fast breathing, fast heart rate, sweating, muscle stiffness and drowsiness or sleepiness or confusion, difficulty in walking, shake or unusual muscle movements which you cannot control. In rare cases there may be rolling of the eyes. These could be signs of a serious condition known as neuroleptic malignant syndrome,
- if you get any pain in your chest or legs, or begin to have breathing difficulties. These could be signs of a blood clot,
- if you get a painful erection of the penis unrelated to sexual activity that will not go away,
- if you notice yellowing of your skin or eyes and your urine becomes darker in colour, high temperature, feel tired, lose your appetite, have stomach pain and feel sick. These could be signs of liver or pancreas problems,
- if you have fits (seizures),
- diabetes or the worsening of diabetes occasionally associated with ketoacidosis (ketones in the blood and urine shown in tests) or falling into a coma,
- if you have abnormal heart beat including a faster or slower than usual heart rate,
- difficulty in controlling urine (urinary incontinence),
- lung infection (pneumonia).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The following side effects have been frequently reported:

- Weight gain or feeling more hungry,
- sleepiness,
- dizziness,
- headache,
- restlessness,
- loss of strength,
- agitation,
- abnormal manner of walking (gait),
- falls,
- problems with speech,
- parkinsonism (a syndrome characterised by trembling, stiffness and balance disorder, postural instability),
- hallucinations,
- water retention leading to swelling of the hands, ankles or feet,
- dry mouth,
- constipation,
- rash,
- increases in the levels of prolactin in the blood (found by blood test).

The following side effects have been reported less frequently:

- Changes in the levels of some blood cells and circulating fats (found through blood tests),
- anxiety,
- mood changes (feeling high or hostile),

- nervousness,
- stuttering,
- sensitivity to sunlight,
- extreme tiredness.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF PREXOLAN IM

Store at or below 25 °C.

Protect from light and moisture.

After reconstitution with sterile water for injection: Stable for one hour when stored at or below 25 °C. Do not freeze.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF PREXOLAN IM

1 x 7 ml clear Type 1 glass vial containing a yellow lyophilised powder is sealed with a bromobutyl rubber stopper together with an aluminium flip off cap.

IDENTIFICATION OF PREXOLAN IM

Yellow lyophilised spongy powder.

Reconstituted solution: Clear, yellow solution free of foreign particles.

REGISTRATION NUMBER

43/2.6.5/0911

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

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